

Applicant:

Kenneth Beaman

Appl. No.:

10/774,708

Conf. No.:

9549

Filed:

February 9, 2004

Title:

COMPOSITIONS AND METHOD TO MODULATE IMMUNE AND

**INFLAMMATORY RESPONSES** 

Art Unit:

Unknown

Examiner:

Unknown

Docket No.:

112461-021

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

### INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 37 C.F.R. 1.97, and 37 C.F.R. 1.98, Applicants request that a citation and examination of the references cited below, and on the attached PTO-1449 form, be made during the course of examination of the above-identified application for United States patent. Pursuant to the Official Gazette Notice dated August 5, 2003, copies of the cited U.S. patents and patent applications are not included as this application was filed after June 30, 2003. However, copies of all other cited references are included with this form.

## **U.S. PATENT DOCUMENTS**

Document No.	<u>Date</u>	<u>Inventor</u>
5,196,526	March 23, 1993	Beaman
6,133,434	October 17, 2000	Buell et al.
6,524,825	February 25, 2003	Mizzen et al.

#### FOREIGN PATENT DOCUMENTS

Document No.	<u>Date</u>	Country
WO 95/33048	December 7, 1995	PCT

#### **OTHER DOCUMENTS**

Boomer, J.S., et al., Regeneration and tolerance factor is expressed during T-lymphocyte activation and plays a role in apoptosis. Hum Immunol, 2001. 62(6): p. 577-88.

Boomer, J.S., et al., Regeneration and tolerance factor's potential role in T-cell activation and apoptosis. Hum Immunol, 2000. 61(10): p. 959-71.

- DuChateau, B.K., et al. *Increased expression of regeneration and tolerance factor in individuals with human immunodeficiency virus infection*. Clin. Diagn. Lab Immunol., 1999 March. 6(2): 193-8. Abstract
- Filippini, A., et al., Ecto-ATPase activity in cytolytic T-lymphocytes. Protection from the cytolytic effects of extracellular ATP. J Biol Chem, 1990. 265(1): p. 334-40.
- Gargett, C.E., J.E. Cornish, and J.S. Wiley, ATP, a partial agonist for the P2Z receptor of human lymphocytes. Br J Pharmacol, 1997. 122(5): p. 911-7.
- Granstein, R., *The skinny on CD39 in immunity and inflammation*. Nature Medicine, April, 2002. Vol. 8, No. 4: p.336-338.
- Labasi JM, P.N., Donovan C, McCurdy S, Lira P, Payette MM, Brissette W, Wicks JR, Audoly L, Gabel CA., Absence of the P2X7 receptor alters leukocyte function and attenuates an inflammatory response. J Immunol, 2002. 168(12)(Jun 15): p. 6436-45.
- Lee, C. et al., Cloning of a cDNA for a T Cell Produced Molecule with a Putative Immune Regulatory Role. Molecular Immunology, 1990. Vol. 27, No. 11, p.1137-1144.
- Lee, G. W., Boomer, J.S., Gilman-Sachs, A., Chedid A., Gudelj, L., Rukavina, D. and Beaman, K. D. Regeneration and tolerance factor of the human placenta induces IL-10 induction. Eur J Immunol, 2001. 31: p. 687-691.
- Mandal, M. and K.D. Beaman, Purification and Characterization of a Pregnancy-Associated Protein: TJ6s. AJRI, 1995. 33:60-67.
- Mizumoto, N., et al., CD39 is the dominant Langerhans cell-associated ecto-NTPDase: modulatory roles in inflammation and immune responsiveness. Nat Med, 2002. 8(4): p. 358-65.
- Pizzo, P., et al., Extracellular ATP causes lysis of mouse thymocytes and activiates a plasma membrane ion channel. Biochem. J., 1991. 274: p. 139-144.
- Rodriguez, A., et al., Lysosomes Behave as Ca<sup>2+</sup> -regulated Exocytic Vesicles in Fibroblasts and Epithelial Cells. The Journal of Cell Biology, 1997. Vol. 137: p. 93-103.
- Toyomura, T., et al., Three subunit a isoforms of mouse vacuolar H(+)-ATPase. Preferential expression of the a3 isoform during osteoclast differentiation. J Biol Chem, 2000. 275(12): p. 8760-5.
- Wiley, J.S., et al. Partial agonists and antagonists reveal a second permeability state of human lymphocyte P2Z/P2X7 channel. The American Physiologicial Society, 1998. C1224-C1232.

Wiley et al., The  $P_{2z}$ -purinoceptor of human lymphocytes: actions of nucleotide agonists and irreversible inhibition by oxidized ATP. Br. J. Pharmacol. 1994 112, 946-950.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,

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BY

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Dated: June 9, 2004

# IN FORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)

Atty Docket No.	Application No.			
112461-021	10/774,708			
Applicant				
Kenneth	Beaman			
Filing Date	Group			
February 9, 2004	Unknown			

PTO Form 1449

SALE MARKET		U.S. PATEN	NT DOCUMENTS	3		
Examiner's Initials	Document Number	Publication Date	Inventor	Class	Subclass	Filing Date If Appropriate
	5,196,526	March 23, 1993	Beaman			
	6,133,434	October 17, 2000	Buell et al.			
	6,524,825	February 25, 2003	Mizzen et al.			
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FOREIGN PATENT DOCUMENTS							
Examiner's	Document	Publication				Trans	lation
Initials	Number	Date	Country	Class	Subclass	Yes	No
	WO 95/33048	December 7, 1995	PCT				
,							

Examiner's	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
Initials	
	Boomer, J.S., et al., Regeneration and tolerance factor is expressed during T-lymphocyte activation and plays a role in apoptosis. Hum Immunol, 2001. 62(6): p. 577-88.
	Boomer, J.S., et al., Regeneration and tolerance factor's potential role in T-cell activation and apoptosis. Hum Immunol, 2000. 61(10): p. 959-71.
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	Gargett, C.E., J.E. Cornish, and J.S. Wiley, ATP, a partial agonist for the P2Z receptor of human lymphocytes. Br J Pharmacol, 1997. 122(5): p. 911-7.
	Granstein, R., <i>The skinny on CD39 in immunity and inflammation</i> . Nature Medicine, April, 2002. Vol. 8, No. 4: p.336-338.

Examiner:	Date Considered:
*Examiner: Initial if citation considered, whether or not Draw line through citation if not in conformance and no	
communication to applicant.	

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PTO Form 1449

Initials	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	Labasi JM, P.N., Donovan C, McCurdy S, Lira P, Payette MM, Brissette W, Wicks JR, Audoly L, Gabel CA., Absence of the P2X7 receptor alters leukocyte function and attenuates an inflammatory response. J Immunol, 2002. 168(12)(Jun 15): p. 6436-45.
	Lee, C. et al., Cloning of a cDNA for a T Cell Produced Molecule with a Putative Immune Regulatory Role. Molecular Immunology, 1990. Vol. 27, No. 11, p.1137-1144.
	Lee, G. W., Boomer, J.S., Gilman-Sachs, A., Chedid A., Gudelj, L., Rukavina, D. and Beaman, K. D. Regeneration and tolerance factor of the human placenta induces IL-10 induction. Eur J Immunol, 2001. 31: p. 687-691.
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	Pizzo, P., et al., Extracellular ATP causes lysis of mouse thymocytes and activiates a plasma membrane ion channel. Biochem. J., 1991. 274: p. 139-144.
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	Wiley et al., The P <sub>2z</sub> -purinoceptor of human lymphocytes: actions of nucleotide agonists and irreversible inhibition by oxidized ATP. Br. J. Pharmacol. 1994 112, 946-950.

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\*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT (Under 37 CFR 1.97(b) or 1.97(c))  Docket No. 112461-21								
In Re Application Of:	Kenneth Beaman	JUN 1 4 20	W 102 102					
Serial No.	Serial No. Filing Date Examiner கோட்ட Group Art Ur							
10/774,708	February 9, 2004	Unknown	Unknown					
Title: COMPOSITIONS	Title: COMPOSITIONS AND METHOD TO MODULATE IMMUNE AND INFLAMMATORY RESPONSES							
	Commiss P.C	ddress to: sioner for Patents D. Box 1450 a, VA 22313-1450						
	37 C	FR 1.97(b)						
of a national ap three months of application; befo	plication other than a continued the date of entry of the national ore the mailing of a first Office Ac	herewith is being filed within three prosecution application under 37 d stage as set forth in 37 CFR 1.49 stion on the merits, or before the maxamination under 37 CFR 1.114.	CFR 1.53(d); within 1 in an international					
	37 (	CFR 1.97(c)						
CFR 1.97(b), p Final Action un	rovided that the Information Disc	d herewith is being filed after the per closure Statement is filed before the if Allowance under 37 CFR 1.311 and is accompanied by one of:	ne mailing date of a					
☐ the state	ment specified in 37 CFR 1.97(e)	· •						
	OR							
☐ the fee so	the fee set forth in 37 CFR 1.17(p).							

TRANSMITTAL OF	TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT. Docket No.								
	nder 37 CFR 1.97(b) or 1.9	7(c))	Docket No. 112461-21						
In Re Application:	enneth Beaman	JUN 1 4 2004	E GENERAL STATES						
Serial No.	Filing Date	Examiner	Group Art Unit						
10/774,708	February 9, 2004	Unknown	Unknown						
COMPOSITIONS	COMPOSITIONS AND METHOD TO MODULATE IMMUNE AND INFLAMMATORY								
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as described belo  Charge th Credit any Charge a Certificate of 7	☐ Credit any overpayment.  ☐ Charge any additional fee required.  ☐ Certificate of Transmission by Facsimile*  ☐ Certificate of Mailing by First Class Mail  ☐ I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States  ☐ Patent and Trademark Office (F:  ☐ I certify that this document and fee is being deposited on June 9, 2004 with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.								
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		Renee Street							
Typed or Printed N	lame of Person Signing Certificate	Typed or Printed Name of Person	n Mailing Certificate						
*This certificate may only be used if paying by deposit account.  Dated: June 9, 2004  Signature									
Ted J. Barthel									
Reg. No. 48,769	Reg. No. 48,769								
P.O. Box 1135 Chicago, IL 60690-1135									
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